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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,836	05/10/2006	Junho Chung	Q94845	2218

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EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

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12/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,836	CHUNG ET AL.	
	Examiner	Art Unit	
	Sharon Wen	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/06/2007, 11/30/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *1-4,9 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 09/26/2007, has been entered.

2. Claims 1-10 are pending.

Claims 1-4 and 9-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim.

In view of allowability of claims 7-8, a telephone call was place on 11/26/2007 to Applicant's representative, Sunhee Lee, during which Examiner proposed an Examiner's Amendment and cancellation of claims 5-6 in order to place claims 7-8 in condition for allowance. Ms. Lee indicated, on 11/30/2007, that Applicant would prefer to see the grounds for rejecting claims 5-6 thus have an opportunity to respond to those grounds.

Claims 5-8 are currently under examination as they read on a neutralizing antibody.

Priority

3. Applicant's amendment to the specification, filed 09/26/2007, to update the claim for priority has been entered.

Applicant's claim for foreign priority from Korean patent application No. 10-2003-0079482, filed 11/11/2003, is acknowledged. However there does not appear to be a certified translation of the priority document. Therefore, Examiner cannot determine whether Korean patent application No. 10-2003-0079482 provides sufficient written support for claims 5-8 of the instant application.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 05/10/2006 is being considered by the examiner.

Specification

5. Applicant's amendment to the specification filed 09/26/2007 to correct the use of trademark has been entered.

Claim Objections

6. The previous claim objection has been withdrawn in view of Applicant's amendment, filed 09/26/2007.

Claim Rejections - 35 USC § 101

7. The previous claim rejection under 35 USC 101 has been withdrawn in view of Applicant's amendment, filed 09/26/2007.

Claim Rejections - 35 USC § 112

8. The previous claim rejections under 35 USC 112, first and second paragraphs, have been withdrawn in view of Applicant's amendment, filed 09/26/2007.

The following new grounds of rejection are necessitated by Applicant's amendment to the claims, filed 09/26/2007.

9. Currently amended claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is insufficient written description of the genus encompassed by the recitation of "a receptor"

There is insufficient written description of the claimed genus of "receptors" in the absence of defining the relevant identifying characteristics such as the structure of other physical and/or chemical characteristics of the claimed genus.

The present claims encompasses a genus of receptors to which hepatocyte growth factor (HGF) that binds. Under the broadest reasonable interpretation, the recitation of "a receptor" encompasses a genus of molecules to which HGF binds.

However the instant specification does not appear to provide a disclosure of which sequence or residues of the compounds are required for the HGF to bind to a receptor and the only disclosed species of the genus of the receptors is c-Met.

A skilled artisan cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus that exhibit this functional property.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C § 112, paragraph 1 "Written Description" requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January, 2001, See especially page 1106 3rd column).

Applicant, at the time of filing, is clearly not in possession of the breadth of claimed "receptors".

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.) Consequently, Applicant was not in possession of the instant claimed invention. See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision. (See page 1115.)

Applicant is invited to amend the claims by reciting "c-Met" as the receptor for HGF as diclosued on page 9 of the specification to obviate this rejection.

Claim Rejections - 35 USC § 102

10. Currently amended claims 5-6 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cao et al. (*PNAS*, 2001, 98:7443-7448, reference of record).

Applicant's arguments, filed 09/26/2007, have been fully considered but have not been found convincing essentially for the reasons of record.

In response to Applicant's argument asserting that the teaching by the Cao reference on that three neutralizing monoclonal antibodies are needed to neutralize HGF activity does not anticipate the technical feature of the present invention, i.e., a single monoclonal antibody capable of inhibiting the HGF activity, the following is noted:

The instant claims are drawn to a neutralizing antibody binding to an epitope of HGF, which reads on any neutralizing antibody that has neutralizing activity to inhibit HGF activity. Although Cao et al. teach a minimal of three neutralizing antibodies are required to inhibit the activity, i.e., Met-HGF signaling pathway in vitro, under the broadest reasonable interpretation of the claims, the three antibodies contribute to the neutralization activity, thus any one of the three antibodies meets this aspect of the claim, i.e., a neutralizing antibody binding to an epitope of HGF.

With regard to the newly added limitation, "to inhibit the HGF from binding to a receptor of the HGF", it is noted that the limitation provides a characterization of the neutralizing antibody. Cao et al. do not teach the neutralizing antibodies to inhibit the HGF from binding to a receptor of the HGF, per se. However, the reference teaches that HGF activity comes from binding to its receptor, Met, also known as c-Met, which leads to Met activation that can be observed via Madin-Darby canine kidney (MDCK) scatter assay and branching morphogenesis assay with SK-LMS-1 cells. Given that the reference teaches that the neutralizing antibodies were raised against HGF (see paragraph bridging pages 7443-7444); that the antibodies inhibited MDCK scattering and SK-LMS-1 branching morphogenesis (see pages 7444-7445, **Results**); and that two of the three antibody binding sites on HGF appear to be in the Met receptor binding sites (see page 7447, right column, lines 1-5), one of ordinary skill and in the art would have immediately envisaged that prior art antibodies would inherently inhibit the HGF from binding

to a receptor of the HGF.

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

With regard to the recitation, "the epitope being a polypeptide of the amino acid sequences of SEQ ID NO: 32 or 33", it is noted that sequences set forth in SEQ ID NOs 32 and 33 do not appear to be part of HGF protein. The sequences are derived from a peptide library screening to which the antibody of the present invention binds (see Example 8 on pages 16-17 of the specification). As the instant claims are drawn to a neutralizing antibody "which specifically binds to an epitope of HGF", under the broadest reasonable interpretation, the claim reads on an that binds HGF and cross-react with SEQ ID NO: 32 or 33.

It is well known in the art that antibodies inherently have cross-reactivity as evidenced by Bost et al. (*Immunological Investigations*, 1988, 17:577:586, see entire document), showing that antibodies can be specific and cross-react with the antigen. For example, antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (e.g., "Results, page 579). As further evidenced by Bendayan (*The Journal of Histochemistry and Cytochemistry*, 1995, 43:881-886, see entire document), the specific reactivity of a monoclonal antibody can be highly specific yet cross-react with antigens from different species or even distinct proteins not related to the original antigen (page 886, last paragraph).

Since the Office does not have a laboratory to test the reference antibody, it is Applicant's burden to show that the reference antibody does no bind to SEQ ID NO: 32 or 33.

Applicant's arguments have not been persuasive.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

The introduction of the evidentiary references of Bost and Bendayan is necessitated by Applicant's amendment, filed 09/26/2007.

Allowable Subject Matter

11. The following is a statement of reasons for the indication of allowable subject matter:

the amino acid sequences of VH and VL regions of the antibodies set forth in claims 7-8 appear to be free of the prior art.

Conclusion

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Wen whose telephone number is (571) 270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Wen
Patent Examiner
December 4, 2007

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PRIMARY EXAMINER
TC 1600
12/10/07